

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated April 13, 2004 are respectfully requested. Applicants petition the Commissioner for a 1-month extension of time. A separate petition accompanies this amendment.

I. Amendments

A. In the Specification

The specification is amended to correct obvious typographical errors.

B. In the Claims

Claims 1, 27, and 59 are amended to recite that each sensor member is connected to a separate energy source. Applicants first direct the Examiner to page 10, lines 5-10, where impedance measurement theory is described, specifically that an excitation current is applied across the tissue and measured. On page 20, lines 1-3, and in Figure 4a, an embodiment is described where the sensing members can be connected to a power supply. Applicants further direct the Examiner to page 2, lines 15-19, page 13, lines 29-30, page 30, lines 23-24, and page 35, lines 1-3, where resilient members are described as either electrodes or sensor members based on their function. Applicants finally direct the Examiner to page 31, lines 18-19, where the electrodes are described as including sensing members. As seen on page 37, lines 7-11, the electrodes may be independently coupled to power sources. Thus, one of skill in the art would clearly recognize that the sensing members may be independently coupled to different power sources.

Claims 4 and 64 are amended to improve readability and correct typographical errors.

No new matter is added by way of these amendments.

II. Rejection under 35 U.S.C. § 112, second paragraph

Claim 64 was rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which

the applicant regards as the invention. Applicants have amended the claim in accord with the Examiner's kind suggestion. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

III. Rejection under 35 U.S.C. § 102

Claims 1-4, 6, 7, 10-13, 15-18, and 21-25 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Gough *et al.* (U.S. Patent No. 5,735,847).

These rejections are respectfully traversed.

A. The Present Invention

The present invention, as embodied by amended claim 1, relates to a method for detecting and treating a tumor using tissue localized volumetric impedance measurements. The method comprises (i) providing an impedance measurement apparatus, (ii) positioning the apparatus at a selected tissue site, (iii) deploying the impedance array to define a sample volume, (iv) utilizing the impedance array to make impedance measurements through a plurality of conductive pathways, (v) determining a tissue condition of the sample volume utilizing information from the impedance measurements, and (vi) delivering energy from the energy delivery device to ablate or necrose at least a portion of the tumor.

The impedance measurement apparatus includes an impedance array having a plurality of resilient members being positionable in an elongated delivery device and being deployable with curvature. At least one of the plurality of resilient members is a sensor member for determining impedance, where each sensor member is operatively connected to a separate energy source. At least one of the plurality of resilient members is an electrode operatively coupled to an energy source.

B. The Prior Art

GOUGH ET AL. relate to a multiple arm device including a primary arm with a longitudinal axis, and a secondary arm coupled to the primary arm. The secondary arm is configured to be deployed in a direction that is lateral to the longitudinal axis with at

least one radius of curvature. The device may further include a multiplexer coupled to the primary antenna, the secondary antenna, and the energy source to multiplex between the primary and secondary antennas.

C. Analysis

According to the M.P.E.P. § 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

Gough *et al.* fail to teach providing an impedance measurement apparatus as in the present invention. As noted above, the impedance measurement apparatus includes a plurality of resilient members where at least one of the resilient members is a sensor member and each sensor member is operatively connected to a separate energy source. Gough *et al.* make no mention of a separate energy source for any of the deployable elements.

Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. § 102 has not been met. Withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

IV. Rejections under 35 U.S.C. §103

Claims 5, 8, 9, 14, 19, 20, 26-44, and 48-63 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.* in view of Pearlman (U.S. Patent No. 5,810,742).

Claim 45 was rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.* in view of Pearlman and further in view of Pacela (U.S. Patent No. 3,871,359).

Claims 46 and 47 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.* in view of Pearlman and further in view of Kun *et al.* (U.S. Patent No. 5,807,272).

These rejections are respectfully traversed.

A. The Present Invention

The present invention is described above. Additionally, independent claim 27 relates to a method for detecting and treating a tumor including a step of providing an apparatus including an impedance sensor array comprising a plurality of sensor members, where each sensor member is operatively connected to a separate energy source. Further, independent claim 59 recites method of detecting and treating a tumor utilizing volumetric complex impedance measurement including a step of providing a tissue diagnosis and treatment apparatus including an impedance sensor array comprising a plurality of sensor members, where each sensor member is operatively connected to a separate energy source.

B. The Prior Art

GOUGH ET AL. is described above.

PEARLMAN describes an apparatus for identification of tissue type in an impedance image. The apparatus may include a laparoscopic or endoscopic impedance probe, preferably formed on a flexible, extendible paddle. The system measures impedance between the individual sensing elements and some reference point at some other place on the body.

PACELA describes an impedance measuring apparatus for measuring first and second electrical impedances. The apparatus is a bilateral impedance plethysmograph designed for the simultaneous measurement of two symmetrical portions of living subjects, i.e. for measurement or monitoring arterial or venous blood flow. The apparatus uses a dual channel or bilateral voltage measurement across two impedances or two portions of one impedance in response to a single constant magnitude alternating current. The apparatus includes a single common constant magnitude alternating current source.

KUN ET AL. describe an impedance spectroscopy system for tissue status monitoring and measurement. The method comprises applying electrical energy to tissue to be analyzed and detecting the spectral response of the tissue to the energy. The preferred electrode configuration uses two outer source surface-spot electrodes connecting the tissue to the constant current source. Inner detection electrodes are then used to monitor the resulting voltage at the tissue (Col. 4, lines 56-61).

C. Analysis

1. Legal Standard

According to the MPEP § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations."

2. Rejection over Gough et al. in view of Pearlman

As noted above, Gough *et al.* fail to teach providing an apparatus where each sensor member is operatively connected to a separate energy source.

The teaching in Pearlman does not make up for this deficiency, as Pearlman makes no mention of an apparatus where each sensor member is operatively connected to a separate energy source.

Thus, nowhere does either reference, taken alone or in combination, show or suggest providing an apparatus where each sensor member is operatively connected to a separate energy source.

3. Rejection over Gough et al. in view of Pearlman, and further in view of Pacela

As noted above, Gough *et al.* and Pearlman each fail to teach providing an apparatus where each sensor member is operatively connected to a separate energy source.

The teaching in Pacela fails to make up for this deficiency. The apparatus of Pacela includes a single common constant magnitude alternating current source (Col. 9, lines 15-17). Pacela fails to make any mention of providing an apparatus where each sensor member is operatively connected to a separate energy source.

Thus, nowhere does any of the references, taken alone or in combination, show or suggest providing an apparatus where each sensor member is operatively connected to a separate energy source.

4. Rejection over Gough et al. in view of Pearlman, and further in view of Kun et al.

The deficiencies of Gough *et al.* and Pearlman are detailed above.

Kun *et al.* fail to make up for this deficiency. The Kun *et al.* reference is cited for a teaching of the use of locus values and makes no mention of providing an apparatus where each sensor member is operatively connected to a separate energy source.

Thus, nowhere does any of the references, taken alone or in combination, show or suggest providing an apparatus where each sensor member is operatively connected to a separate energy source.

In view of the above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

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The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,



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